

Etanercept (Enbrel®)

This sheet is about exposure to etanercept in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is etanercept?

Etanercept is a prescription medication used to treat some autoimmune diseases such as rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis, and juvenile rheumatoid arthritis. For more information, please see the MotherToBaby fact sheets on rheumatoid arthritis at <https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/>, ankylosing spondylitis at <https://mothertobaby.org/fact-sheets/ankylosing-spondylitis/>, and psoriasis/psoriatic arthritis at <https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/>.

Etanercept is called a tumor necrosis factor (TNF) inhibitor because it binds and blocks TNF. TNF is a substance in the body that causes inflammation in the joints, spine, and skin. Etanercept is sold under the brand name Enbrel®.

Sometimes when people find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

I am taking etanercept, but I would like to stop taking it before becoming pregnant. How long does the drug stay in my body?

People eliminate medications at different rates. In healthy adults, it takes about three to four weeks after the last injection of etanercept, on average, for most of the medication to be gone from the body.

I take etanercept. Can it make it harder for me to get pregnant?

There are no reports linking etanercept to trouble getting pregnant. Etanercept is being studied to see if it may be used with other therapies to improve the success rates of certain fertility treatments in some people.

Does taking etanercept increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. A study published in 2017 found that 337 people treated with etanercept during their pregnancy did not have a higher rate of miscarriage compared to similar groups of people who were not treated with etanercept in their pregnancy. A study that surveyed rheumatologists (doctors that are trained to diagnose and treat pain in the bones, joints, and muscles) reported no increase in miscarriage in 417 people exposed to etanercept or another TNF inhibitor during pregnancy. About one third of these people continued to take the medication throughout pregnancy.

Does taking etanercept increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. Most studies on etanercept use during pregnancy do not suggest an increase in the chance of birth defects above the background risk.

The authors of a study published in 2018 stated that there was no increase in birth defects compared to people not using a TNF inhibitor. At least six smaller studies (each looking at fewer than 100 individuals taking etanercept in the first trimester) have not found an increased chance for a pattern of birth defects.

There are two studies that included 319 and 344 infants of people who had taken etanercept during pregnancy that reported a higher rate of birth defects compared to the infants of individuals with autoimmune diseases who did not take a TNF inhibitor during pregnancy. However, there was no pattern of birth defects, which can show a link between the medication and the birth defects. Also, the people who used etanercept might have had more severe disease than the people who did not use it, which could have affected their outcomes.

A 2015 study reported on 495 pregnancies exposed to TNF inhibitors, with 140 of those exposed to etanercept. This study found a small increased chance of birth defects and preterm delivery (delivery before 37 weeks of pregnancy)

when looking at all of the TNF inhibitor medications. However, the study did not compare these pregnancy outcomes to those who had similar medical conditions but were not taking TNF inhibitors. This study cannot determine if the problems reported were due to the medications or the diseases being treated.

In summary, most studies looking at etanercept use during pregnancy have not shown an increased chance for a pattern of birth defects. It is also thought that a large amounts of etanercept is unlikely to reach the developing baby during the first trimester when most of the baby's major organs and body structures are forming.

Does taking etanercept in pregnancy increase the chance of other pregnancy related problems?

Two studies found that people with rheumatoid arthritis, chronic inflammatory arthritis or psoriasis were more likely to have preterm delivery and have babies with lower birth weight than people who did not have these medical conditions. This was true for the people with medical conditions who used etanercept and those who did not. This suggests that the autoimmune conditions themselves, or use of another medication besides etanercept, increased the chance for having a preterm delivery or low birth weight baby, rather than the use of etanercept specifically.

Like other TNF inhibitors, etanercept can cross the placenta and reach the developing baby beginning in the second trimester and even more so in the third trimester. The placenta is a temporary organ that develops during pregnancy and works as the blood connection between mother and baby. Limited information looking at the use of etanercept in the third trimester has not shown increased risks to the baby.

Does taking etanercept in pregnancy affect future behavior or learning for the child?

Studies have not been done to see if etanercept can cause behavior or learning issues for the child.

Can my baby receive vaccines before one year of age if I take etanercept later in pregnancy?

Noninfectious (non-live) vaccines can be given to a baby even if etanercept is present in his/her blood. Most vaccines given in the first 6 months of life are noninfectious.

Live vaccines usually contain a mild (attenuated) form of the virus or bacteria that it vaccinates against. Live vaccines always carry a small chance a person could contract the infection from the vaccine. Live vaccines are usually not given to people using TNF inhibitors like etanercept. Vaccines protect babies from getting common infections that can sometimes cause serious or even life-threatening illness. In the United States, the rotavirus vaccine is the only live vaccine given to infants less than one year of age. Rotavirus is one of the leading causes of vomiting and severe diarrhea in children. Your pediatrician or healthcare provider can discuss the risks and benefits of live vaccines with you.

Breastfeeding while taking etanercept:

Etanercept is a large protein, so it is thought that very little of the medication could pass into breast milk. Four case reports support that etanercept levels in breast milk are very low. Two of these reports looked at the amount of etanercept in the baby's blood from breast milk and found the levels were undetectable. One of the infants was followed to three years of age and no harmful effects were reported.

In addition to expected low levels in breast milk, this medication is also not well absorbed from the gut. So any etanercept that gets into breast milk would most likely pass through the baby's body without getting into their bloodstream. Babies born before 37 weeks of pregnancy (preterm) with digestive systems that are not fully developed may be able to absorb more of the medication through breast milk.

The information on taking etanercept while nursing a child is very limited. A small study looked at five breastfeeding infants of a people who were treated with etanercept and compared them to breastfeeding infants of people who had the same medical conditions but were not being treated with a TNF inhibitor. The study found no differences in the infants' growth, development, response to vaccinations, or illnesses in the first year of life.

Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a male takes etanercept, could it affect fertility (ability to get partner pregnant) or increase the chance of birth defects?

Two small studies reported that partners taking etanercept for spondylarthritis (SpA) had the same sperm quality as partners with SpA who were not taking a TNF inhibitor. This early information suggests taking etanercept would not

affect a male's fertility. In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/>.

MotherToBaby is currently conducting a study looking at autoimmune diseases and the medications used to treat autoimmune diseases in pregnancy. If you are interested in taking part in this study, please call 1-877-311-8972 or sign up at <https://mothertobaby.org/join-study/>.

Please click here to view references.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at [MotherToBaby.org](https://mothertobaby.org).

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